REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

Rejections under 35 U.S.C. 102

Claims 1-14 have been rejected under 35 U.S.C. 102(e) as being anticipated by Doscher et al. (US 6,846,323).

Claims 1-14

Claims 1-14 relate to methods for treating vulnerable plaque. Vulnerable plaques are defined as plaques prone, in the presence of an appropriate trigger, to events such as ulceration rupture, erosion, or thrombus. It has been found that the rupture-prone (i.e., vulnerable plaques) typically have a thin fibrous cap, numerous inflammatory cells, a substantial lipid core, and few smooth muscle cells. Many of these so-called "vulnerable plaques" do not block the arteries and do not limit the blood flow through the blood vessels or cause any of the symptoms which lead physicians to treat heart disease. On the other hand, much like an abscess, they are ingrained in the arterial wall, so that they are undetectable by traditional methods.

The methods of Claims 1-14 can be used to directionally deliver therapeutic agents into the blood stream for local delivery to the walls of the blood vessels downstream of the implantation site to treat the vulnerable plaque. The delivery of the agent primarily luminally into the inner lumen of the artery at the stent implantation site as claimed can stabilize the plaque downstream reducing the occurrences of ruptures and healing the raw exposed tissues from a previous rupture. The delivery of the vulnerable plaque stabilizing drug primarily in the luminal direction allows the possibility to deliver an additional antirestenotic drug murally or toward the vessel wall.

Doscher et al. describes a specific method for treatment of vulnerable plaque which involves implanting a stent like structure (SLS) and heating the implanted structure. Doscher et al. does mention at column 7, lines 52-57, that "the SLS may be augmented with drugs." However, Doscher et al. does not say anything about the direction of delivery of the drug and specifically does not teach or suggest delivery of a therapeutic agent primarily to a luminal side

of the medical device as claimed in Claim 1. Accordingly, Doscher, et al. cannot anticipate claims 1-26.

Claims 15-26

Claims 15-26 have been rejected as anticipated by Castro et al. (US 6,616,765) Castro et al. describes a method of coating stents with therapeutic substances. Castro et al. does not mention vulnerable plaque or the luminally directed delivery of an agent as claimed in Claim 15. Castro et al. mentions treatment of atherosclerotic plaque with angioplasty. (Column 1, line 25) However, Castro et al. clearly does not teach or suggest the use of an expandable medical device to deliver a therapeutic agent for treatment of vulnerable plaque.

Furthermore, the structures of Castro et al. are designed to deliver drug murally (outward from the stent) and not luminally as claimed in Claim 15. As shown throughout Castro et al. the patterns of drug are sprayed onto the outside of the stent. Thus, the stents of Castro et al. can provide primarily mural delivery, but not primarily luminal delivery as claimed in Claim 15. Therefore, Claims 1-26 cannot be anticipated by Castro et al.

Claims 14 and 25

Claims 14 and 25 relate to a method and implantable medical device in which an agent for treatment of vulnerable plaque is delivered *primarily luminally* and an antirestenotic agent is delivered *primarily murally*. This directional delivery of two agents in opposite directions to treat vulnerable plaque and restenosis is not taught or suggested by Doscher et al. or Castro et al. For this additional reason, Claims 14 and 25 are allowable.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a further telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below. The Commissioner is authorized to charge any fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-3100.

Respectfully submitted,
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